REMARKS

I. Introduction

In response to the Office Action dated June 15, 2004, claims 23 and 41 have been amended. Claims 23-58 remain in the application. Re-examination and re-consideration of the application, as amended, is requested.

II. Claim Amendments

Applicants' attorney has made amendments to the claims and added new claims as indicated above. The amendments to the claims introduce no new matter. Support for elements such as a control system including a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending the plurality of medication delivery profiles can be found, for example, in paragraphs **[0067] – [0071]**.

III. The Cited References and the Subject Invention

A. Dastur et al., U.S. Patent No. 5,772,635

U.S. Patent No. 5,772,635 teaches a medication infusion system having an integrated dose rate calculation feature for selectively assigning values to a plurality of infusion parameters and automatically calculating an infusion rate from the selected parameters. A stored list of drug names have associated dose rate and concentration units that are automatically set when a drug name is selected from the list. The dose rate calculation feature may also be used during infusion to titrate the dosage being delivered to the patient for improved therapeutic results. As the subject matter technology described in this reference is directed to manual "Start/Stop" controls used to activate and suspend infusion regimes, U.S. Patent No. 5,772,635 provides no teaching of a system having a programmable control center that includes a temporary suspend of medication delivery and a fully suspended delivery of medication delivery by an infusion pump.

B. Peterson et al., U.S. Patent No. 5,935,099

U.S. Patent No. 5,935,099 teaches a menu driven programmable drug pump, a patient pump, that is linked with a second pump, a caregiver pump, via a communication link. Communication between the patient pump and the caregiver pump allows communication for purposes including

information transferred in the event of an error condition, or a programming update, or a status update. The pumps include programs to operate either pump as a master pump or as a slave pump during pump to pump communications. A disabling structure is provided to the caregiver pump to for disabling the pumping mechanism of caregiver pump such that during pump to pump communications, the pumping mechanism and the pumping protocol is suspended.

C. Larson et al., U.S. Patent No. 5,609,575

U.S. Patent No. 5,609,575 teaches an infusion pump and method of operating an infusion pump in which the user of the infusion pump is prompted to input a number of infusion parameters, which include a dose mode, a drug dose, a drug amount, and a drug volume. After the parameters are input by the user, the infusion pump automatically calculates an infusion rate corresponding to the desired drug dose input by the user. After the actual dose is determined, the infusion pump continuously infuses the patient with the drug at the displayed infusion rate. If the user wishes to temporarily suspend the drug infusion to the patient, the user may cause the infusion pump to transition to the standard hold mold by pressing a pushbutton or key.

D. Fischell, U.S. Patent No. 4,731,051

U.S. Patent No. 4,731,051 teaches an implantable programmable infusion pump (IPIP) including a control means for actuating the pump in a safe and programmable manner. The control means includes a microprocessor, a permanent memory containing a series of fixed software instructions, and a memory for storing prescription schedules, dosage limits and other data. The microprocessor actuates the pump in accordance with programmable prescription parameters and dosage limits stored in the memory. The patient can inhibit or suspend pump operation for a certain number of 1-hour intervals.

E. Lebel et al., U.S. Patent No. 6,659,948

U.S. Patent No. 6,659,948 teaches an implanted medical device (e.g. infusion pump) and an external device that communicate with one another via telemetry messages that are receivable only during windows or listening periods. Each listening period is open for a prescribed period of time and is spaced from successive listening periods by an interval. The device is configured to go in to a

suspend mode, for example, if an unreceived communication deals with an insulin delivery issue that is no longer applicable, thereby canceling the insulin delivery. In U.S. Patent No. 6,659,948, the suspend mode is an operational state of the implantable device where insulin delivery is reduced to a medically insignificant level.

F. The Subject Invention

Embodiments of the claimed invention include systems for delivering medication, comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending the plurality of medication delivery profiles, as well as methods for using such systems.

IV. Applicants' Response to Prior Art Rejections

On page (3) of the Office Action, claims 23 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Dastur et al., U.S. Patent No. 5,772,635 (Dastur), Peterson et al., U.S. Patent No. 5,935,099 (Peterson), Larson et al., U.S. Patent No. 5,609,575 (Larson), and Fischell, U.S. Patent No. 4,731,051 (Fischell). Claims 23 and 41 were rejected under 35 U.S.C. §102(e) as being anticipated by Lebel et al., U.S. Patent No. 6,659,948 (Lebel). On page (4) of the Office Action, claims 24-40 and 42-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dastur, Peterson, Larson, Fischell, and Lebel.

Independent claims 23 and 41 as amended hereinabove recite systems for delivering a medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions capable of separately suspending the plurality of medication delivery profiles (i.e. suspend one delivery profile but not another). As described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. a basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). Consequently, this separate suspend function allows the user to precisely control the delivery of a medication in a

manner that optimizes the physiological concentration of the medication in the user (e.g. the delivery of exogenous insulin in a profile that mimics physiological insulin levels).

As discussed in detail below, Applicants respectfully traverse the rejections because the Dastur, Peterson, Larson and Fischell references fail to teach or suggest a device having a control system that includes a plurality of medication delivery profiles and further allows the user to separately suspend each of these plurality of medication delivery profiles. Applicants further traverse the rejection because the Lebel reference: (1) fails to anticipate the invention recited in the amended claims; and (2) falls under the provisions of 35 U.S.C. 103(c). Applicants' detailed arguments are provided below.

A. APPLICANTS' RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 23 and 41 under 35 U.S.C. §102(b) as being anticipated by Dastur because this disclosure fails to teach a system for delivering medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions that are capable of separately suspending the plurality of medication delivery profiles. Instead, Dastur merely teaches a system having a simple "Start/Stop" control that can be used to completely suspend fluid medication delivery (see e.g. column 10, lines 32-51). Consequently, the suspend function disclosed in the Dastur system is not designed to even distinguish between a plurality of medication delivery profiles, much less separately suspend one or more such medication delivery profiles. As Dastur fails to teach medical devices having the medication delivery control functions that are recited claims 23 and 41 (as amended), this disclosure cannot anticipate the claimed subject matter. For these reasons, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §102(b).

Applicants respectfully traverse the rejection of claims 23 and 41 under 35 U.S.C. §102(b) as being anticipated by Peterson because this disclosure fails to teach a system for delivering medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions that are capable of separately suspending the plurality of medication delivery profiles. Instead, Peterson merely teaches a system having a simple disabling

structure that can be used to completely suspend the pumping mechanism and pumping protocol (see e.g. column 17, lines 59-63). Consequently, the suspend function disclosed in the Peterson system is not designed to even distinguish between a plurality of medication delivery profiles, much less separately suspend one or more such medication delivery profiles. As Peterson fails to teach medical devices having the medication delivery control functions that are recited claims 23 and 41 (as amended), this disclosure cannot anticipate the claimed subject matter. For these reasons, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §102(b).

Applicants respectfully traverse the rejection of claims 23 and 41 under 35 U.S.C. §102(b) as being anticipated by Larson because this disclosure fails to teach a system for delivering medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions that are capable of separately suspending the plurality of medication delivery profiles. Instead, Larson merely teaches a system having simple "Hold" key that can be used to completely suspend fluid delivery (see e.g. column 3, lines 53-63). Consequently, the suspend function disclosed in the Larson system is not designed to even distinguish between a plurality of medication delivery profiles, much less separately suspend one or more such medication delivery profiles. As Larson fails to teach medical devices having the medication delivery control functions that are recited claims 23 and 41 (as amended), this disclosure cannot anticipate the claimed subject matter. For these reasons, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §102(b).

Applicants respectfully traverse the rejection of claims 23 and 41 under 35 U.S.C. §102(b) as being anticipated by Fischell because this disclosure fails to teach a system for delivering medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions that are capable of separately suspending the plurality of medication delivery profiles. Instead, Fischell teaches a system having controls that completely suspend pump operation (and therefore fluid delivery, see e.g. column 21, lines 40-51). Consequently, the suspend function disclosed in the Fischell system is not designed to even distinguish between a plurality of medication delivery profiles, much less separately suspend one or more such medication delivery profiles. As Fischell fails to teach medical devices having the medication delivery control functions

that are recited claims 23 and 41 (as amended), this disclosure cannot anticipate the claimed subject matter. For these reasons, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §102(b).

Applicants respectfully traverse the rejection of claims 23 and 41 under 35 U.S.C. §102(e) as being anticipated by Lebel because this disclosure fails to teach a system for delivering medication comprising an infusion pump and a control system for controlling medication delivery by the infusion pump; wherein the control system includes a plurality of medication delivery profiles and a plurality of suspend functions that are capable of separately suspending the plurality of medication delivery profiles. Instead, Lebel teaches a system having controls that suspends medication delivery to a medically insignificant level (see e.g. column 39, lines 56-60). As Lebel fails to teach medical devices having the medication delivery control functions that are recited in claims 23 and 41 (as amended), this disclosure cannot anticipate the claimed subject matter. For these reasons, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §102(e).

B. APPLICANTS RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. §103(a)

Applicants respectfully traverse the rejection of claims 24-40 and 42-58 as being obvious in view of Dastur because this disclosure fails to teach or suggest a medication delivery system having a control system that provides a plurality of suspend functions that are capable of separately suspending a plurality of medication delivery profiles. Moreover, when the systems and methods disclosed in Dastur are examined in the context of the whole disclosure (as required by M.P.E.P. 2141), it is clear that this reference teaches away from the invention recited in the claims. Specifically, as described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. the basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). In contrast, the Dastur disclosure directs artisans to utilize a medication delivery system having a control system that is explicitly designed to completely suspend the delivery of all fluid medication (via a simple "Start/Stop" control as described at column 10, lines 32-51) and therefore teaches away from the claimed separate suspend functions. Because the Dastur reference teaches away from the claimed invention, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

Applicants respectfully traverse the rejection of claims 24-40 and 42-58 as being obvious in view of Peterson because this disclosure fails to teach or suggest a medication delivery system having a control system that provides a plurality of suspend functions that are capable of separately suspending a plurality of medication delivery profiles. Moreover, when the systems and methods disclosed in Peterson are examined in the context of the whole disclosure (as required by M.P.E.P. 2141), it is clear that this reference teaches away from the invention recited in the claims. Specifically, as described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. the basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). In contrast, the Peterson disclosure directs artisans to utilize a medication delivery system having a control system that is explicitly designed to completely suspend the delivery of all fluid medication (see e.g. column 17, lines 59-63) and therefore teaches away from the claimed separate suspend functions. Because the Peterson reference teaches away from the claimed invention, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

Applicants respectfully traverse the rejection of claims 24-40 and 42-58 as being obvious in view of Larson because this disclosure fails to teach or suggest a medication delivery system having a control system that provides a plurality of suspend functions that are capable of separately suspending a plurality of medication delivery profiles. Moreover, when the systems and methods disclosed in Larson are examined in the context of the whole disclosure (as required by M.P.E.P. 2141), it is clear that this reference teaches away from the invention recited in the claims. Specifically, as described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. the basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). In contrast, the Larson disclosure directs artisans to utilize a medication delivery system having a control system that is explicitly designed to completely suspend the delivery of all fluid medication (column 3, lines 53-63) and therefore teaches away from the claimed separate suspend functions. Because the Larson reference teaches away from the claimed invention, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

Applicants respectfully traverse the rejection of claims 24-40 and 42-58 as being obvious in view of Fischell because this disclosure fails to teach or suggest a medication delivery system having

a control system that provides a plurality of suspend functions that are capable of separately suspending a plurality of medication delivery profiles. Moreover, when the systems and methods disclosed in Fischell are examined in the context of the whole disclosure (as required by M.P.E.P. 2141), it is clear that this reference teaches away from the invention recited in the claims. Specifically, as described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. the basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). In contrast, the Fischell disclosure directs artisans to utilize a medication delivery system having a control system that is explicitly designed to completely suspend the delivery of all fluid medication (column 21, lines 40-51) and therefore teaches away from the claimed separate suspend functions. Because the Fischell reference teaches away from the claimed invention, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

Applicants respectfully traverse the rejection of claims 24-40 and 42-58 as being obvious in view of Lebel because this disclosure fails to teach or suggest a medication delivery system having a control system that provides a plurality of suspend functions that are capable of separately suspending a plurality of medication delivery profiles. Specifically, as described for example in paragraph **[0069]** of Applicants' specification, the separate suspend function recited in the claims is designed to allow the user to suspend one medication delivery profile (e.g. the basal profile) while maintaining another separate medication delivery profile (e.g. a bolus profile). In contrast, the Lebel disclosure directs artisans to utilize a medication delivery system having a control system that suspends medication delivery to a medically insignificant level (see e.g. column 39, lines 56-60). Consequently, the Lebel reference fails to teach or suggest the claimed separate suspend functions, which as noted above, allows the user to precisely control the delivery of a medication in a manner that optimizes the physiological concentration of the medication in the user. Because the claimed separate suspend functions would not have been obvious in view of Lebel's disclosure which directs the user to suspend medication delivery to a medically insignificant level, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

In response to the Examiner's rejection under 35 U.S.C. 103(a) in view of Lebel, Applicants further direct the Examiner's attention to 35 U.S.C. 103(c) which states:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsection (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

As the provisions of 35 U.S.C. 103(c) apply to patent applications filed on or after November 29, 1999, this provision is believed to apply to the instant application (and a copy of the assignment recordation document to Medtronic MiniMed is attached herein as Exhibit A).

In response to the Examiner's specific assertion that "the modification of an infusion system algorithm to consider more than one profile would have been considered an obvious design choice" (page 4 of the Office Action), Applicants further note that obviousness can only be established by modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so (see, M.P.E.P. 2143.01). In this context, Applicants note that the Dastur, Peterson, Larson and Fischell disclosures fail to teach a system designed to deliver a plurality of medication delivery profiles. **As this fundamental control element is not even contemplated by the Dastur, Peterson, Larson and Fischell disclosures, these references cannot provide a teaching, suggestion, or motivation to modify it in order to generate the claimed invention** (i.e. via the claimed suspend function which is designed to separately suspend the plurality of medication delivery profiles). Consequently, the requirement for a finding of obviousness under 35 U.S.C. §103(a) cannot be met. For this reason, Applicants further request the withdrawal of all rejections under 35 U.S.C. §103(a).

Thus, Applicants submit that independent claims 23 and 41 are allowable over Dastur, Peterson, Larson, Fischell, and Lebel. Further, dependent claims 24-40 and 42-58 are submitted to be allowable over Dastur, Peterson, Larson, Fischell, and Lebel in the same manner, because they are dependent on independent claims 23 and 41, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 24-40 and 42-58 recite additional novel elements not shown by Dastur, Peterson, Larson, and Fischell.

IV. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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